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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,365	09/25/2003	R. Douglas Cassel	10071-036-999	3378
20582	7590	06/16/2005	EXAMINER	
JONES DAY 51 Louisiana Aveue, N.W WASHINGTON, DC 20001-2113			KIM, VICKIE Y	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,365

Applicant(s)

CASSEL, R. DOUGLAS

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/04 & 9/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-25 are presented for examination

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly(AN assessment of the ..., 1996).

The claims are drawn to a method of ameliorating pain from a surgically closed wound(e.g. laparoscopy) using an effective amount of bupivacaine via topical application.

Kelly(1996) teaches a method of ceasing pain after laparoscopic procedure using a direct application of bupivacaine into fallopian tubes, see 1st paragraph at page 837. At page 837, 1st paragraph, it teaches direct topical application of diluted bupivacaine instilled into the pelvic peritoneal cavity before the closure of the umbilical port in the procedure.

Thus, all the critical elements are well taught by the cited reference and the claims are met.

Claim Rejections - 35 USC § 103

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or alternatively, under 35 U.S.C. 103(a) as being unpatentable over Zhang(US 6,528,086).

Zhang (US'086, hereinafter) teaches a topical delivery of anesthesia, especially, application of a eutectic mixture of local anesthetic cream into the skin, see col. 1, lines 45-63. US'086 also teaches closed wound, see col.2, lines 19-22. It is noted that eutectic mixture consists of lidocaine and tetracaine, see col. 3, lines 31-32. US'086 also teaches prolonged delivery(see col. 9, lines 32-34) and eutectic mixture utilizing different types of local anesthetics, see col. 11, lines 56-63. Patch application is also taught by the patent as well as other dosage forms including sprays, gels, etc, see column 13, lines 20-28 and col.14, lines 65-67. US'086 further teaches effective amount (0.1-40%) of local anesthetics used in the treatment, see examples , especially table F(formulation II).

Most of elements required by the instant claims are well taught.

The variations including mixture of lidocaine and prilocaine, exclusion of penetration enhancer, application in every 18-48 hours, are considered to be minor variations where these modifications are conventional knowledge and

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routinely practiced in pharmaceutical field in order to determine most effective dosage forms and obtain maximum therapeutic effect, well within the skilled level of the ordinary artisan.

Thus, one would have been readily envisaged how to make such changes to accommodate the needs, or the said variations are readily apparent to skilled artisan. The claimed subject matter is not patentably distinct over the prior art of the record.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6645521 or 6383511. Although the conflicting claims are not identical, they are not patentably distinct from each other because both patented claims and instant claims are directed to substantially same subject matter(i.e. a method of preventing or ameliorating pain form surgical procedure using an

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effective amount of topical anesthetics). Thus, the claims are not patentably distinct over the claims found in those patents.

Conclusion

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
June 13, 2005
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